

31

Westlaw.

Page 1

21 C.F.R. § 101.82

C

Effective: [See Text Amendments]

Code of Federal Regulations Currentness

Title 21. Food and Drugs

Chapter I. Food and Drug Administration,
Department of Health and Human Services
(Refs & Annos)

Subchapter B. Food for Human Consumption

Part 101. Food Labeling (Refs & Annos)

Subpart E. Specific Requirements for
Health Claims (Refs & Annos)**→§ 101.82 Health claims: Soy
protein and risk of coronary heart
disease (CHD).**

(a) Relationship between diets that are low in saturated fat and cholesterol and that include soy protein and the risk of CHD.

(1) Cardiovascular disease means diseases of the heart and circulatory system. CHD is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing CHD. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total

cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in plant foods that contain dietary fiber and other components.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soy protein to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) Significance of the relationship between diets that are low in saturated fat and cholesterol and that include soy protein and the risk of CHD.

(1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL-cholesterol levels. Soy protein, when included in a low saturated fat and cholesterol diet, also helps to lower blood total and LDL-cholesterol levels.

(c) Requirements.

(1) All requirements set forth in § 101.14 shall

21 C.F.R. § 101.82

be met.

(2) Specific requirements--

(i) Nature of the claim. A health claim associating diets that are low in saturated fat and cholesterol and that include soy protein with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets that are low in saturated fat and cholesterol and that include soy protein "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease";

(C) In specifying the substance, the claim uses the term "soy protein";

(D) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol";

(E) The claim does not attribute any degree of risk reduction for CHD to diets that are low in saturated fat and cholesterol and that include soy protein;

(F) The claim does not imply that consumption of diets that are low in saturated fat and cholesterol and that include soy protein is the only recognized means of achieving a reduced risk of CHD; and

(G) The claim specifies the daily dietary intake of soy protein that is necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to the specified daily dietary intake level. The daily dietary intake level of soy protein that has been associated with reduced risk of coronary heart disease is 25 grams (g) or more per day of soy protein.

(ii) Nature of the substance.

(A) Soy protein from the legume seed *Glycine max.*

(B) FDA will assess qualifying levels of soy protein in the following fashion: FDA will measure total protein content by the appropriate method of analysis given in the "Official Methods of Analysis of the AOAC International," as described at § 101.9(c)(7). For products that contain no sources of protein other than soy, FDA will consider the amount of soy protein as equivalent to the total protein content. For products that contain a source or sources of protein in addition to soy, FDA will, using the measurement of total protein content, calculate the soy protein content based on the ratio of soy protein ingredients to total protein ingredients in the product. FDA will base its calculation on information identified and supplied by manufacturers, such as nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein. Manufacturers must maintain records sufficient to substantiate the claim for as long as the products are marketed and provide these records, on written request, to appropriate regulatory officials.

(iii) Nature of the food eligible to bear the claim.

(A) The food product shall contain at least 6.25 g of soy protein per reference amount customarily consumed of the food product;

(B) The food shall meet the nutrient content requirements in § 101.62 for a "low saturated fat" and "low cholesterol" food; and

(C) The food shall meet the nutrient content requirement in § 101.62 for a "low fat" food, unless it consists of or is derived from whole soybeans and contains no fat in addition to the fat inherently present in the

21 C.F.R. § 101.82

whole soybeans it contains or from which it is derived.

(d) Optional information.

(1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease;

(2) The claim may state that the relationship between intake of diets that are low in saturated fat and cholesterol and that include soy protein and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total and LDL-cholesterol";

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that are low in saturated fat and cholesterol and that include soy protein and CHD and the significance of the relationship;

(4) The claim may state that a diet low in saturated fat and cholesterol that includes soy protein is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(5) The claim may state that individuals with elevated blood total and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(6) The claim may include information on the number of people in the United States who

have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO;

(e) Model health claim. The following model health claims may be used in food labeling to describe the relationship between diets that are low in saturated fat and cholesterol and that include soy protein and reduced risk of heart disease:

(1) 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies ___ grams of soy protein.

(2) Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides ___ grams of soy protein.

[64 FR 57732, Oct. 26, 1999]

21 C. F. R. § 101.82, **21 CFR § 101.82**

Current through July 19, 2007; 72 FR 39581

Copr. © 2007

Thomson/West

END OF DOCUMENT

32

Westlaw.

Page 1

21 C.F.R. § 101.83

C

Effective: July 21, 2005

Code of Federal Regulations Currentness

Title 21. Food and Drugs

Chapter I. Food and Drug Administration,
Department of Health and Human Services
(Refs & Annos)

Subchapter B. Food for Human Consumption

Part 101. Food Labeling (Refs & Annos)

Subpart E. Specific Requirements for
Health Claims (Refs & Annos)**→§ 101.83 Health claims: plant
sterol/stanol esters and risk of
coronary heart disease (CHD).**(a) Relationship between diets that include plant
sterol/stanol esters and the risk of CHD.

(1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL) cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/l)) or above and LDL cholesterol levels of 160 mg/dL (4.13 mmol/l) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/l) for total cholesterol, and 130 to 159 mg/dL (3.36 to 4.11 mmol/l) of LDL cholesterol.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also

relatively high in plant foods that contain dietary fiber and other components.

(3) Scientific evidence demonstrates that diets that include plant sterol/stanol esters may reduce the risk of CHD.

(b) Significance of the relationship between diets that include plant sterol/stanol esters and the risk of CHD.

(1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL cholesterol are major modifiable risk factors in the development of CHD.

(2) The scientific evidence establishes that including plant sterol/stanol esters in the diet helps to lower blood total and LDL cholesterol levels.

(c) Requirements--

(1) General. All requirements set forth in § 101.14 shall be met, except § 101.14(a)(4) with respect to the disqualifying level for total fat per 50 grams (g) in dressings for salad and spreads and § 101.14(e)(6) with respect to dressings for salad.

(2) Specific requirements--

(i) Nature of the claim. A health claim associating diets that include plant sterol/stanol esters with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that plant sterol/stanol esters should be consumed as part of a diet low in saturated fat and cholesterol;

21 C.F.R. § 101.83

(B) The claim states that diets that include plant sterol/stanol esters "may" or "might" reduce the risk of heart disease;

(C) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease";

(D) In specifying the substance, the claim uses the term "plant sterol esters" or "plant stanol esters," except that if the sole source of the plant sterols or stanols is vegetable oil, the claim may use the term "vegetable oil sterol esters" or "vegetable oil stanol esters";

(E) The claim does not attribute any degree of risk reduction for CHD to diets that include plant sterol/stanol esters;

(F) The claim does not imply that consumption of diets that include plant sterol/stanol esters is the only recognized means of achieving a reduced risk of CHD; and

(G) The claim specifies the daily dietary intake of plant sterol or stanol esters that is necessary to reduce the risk of CHD and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of plant sterol and stanol esters that have been associated with reduced risk of are:

(1) 1.3 g or more per day of plant sterol esters.

(2) 3.4 g or more per day of plant stanol esters.

(H) The claim specifies that the daily dietary intake of plant sterol or stanol esters should be consumed in two servings eaten at different times of the day with other foods.

(ii) Nature of the substance--

(A) Plant sterol esters.

(1) Plant sterol esters prepared by esterifying a mixture of plant sterols from edible oils with food-grade fatty acids. The plant sterol mixture shall contain at least 80 percent beta-sitosterol, campesterol, and stigmasterol (combined weight).

(2) FDA will measure plant sterol esters by the method entitled "Determination of the Sterol Content in Margarines, Halvarines, Dressings, Fat Blends and Sterol Fatty Acid Ester Concentrates by Capillary Gas Chromatography," developed by Unilever United States, Inc., dated February 1, 2000. The method, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, may be obtained from the Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Nutrition Science and Policy, 5100 Paint Branch Pkwy., College Park, MD 20740, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_loactions.html.

(B) Plant stanol esters.

(1) Plant stanol esters prepared by esterifying a mixture of plant stanols derived from edible oils or byproducts of the kraft paper pulping process with food-grade fatty acids. The plant stanol mixture shall contain at least 80 percent sitostanol and campestanol (combined weight).

(2) FDA will measure plant stanol

21 C.F.R. § 101.83

esters by the following methods developed by McNeil Consumer Healthcare dated February 15, 2000: "Determination of Stanols and Sterols in Benecol Tub Spread"; "Determination of Stanols and Sterols in Benecol Dressing"; "Determination of Stanols and Sterols in Benecol Snack Bars"; or "Determination of Stanols and Sterols in Benecol Softgels." These methods are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Nutrition Science and Policy, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(iii) Nature of the food eligible to bear the claim.

(A) The food product shall contain:

(1) At least 0.65 g of plant sterol esters that comply with paragraph (c)(2)(ii)(A)(1) of this section per reference amount customarily consumed of the food products eligible to bear the health claim, specifically spreads and dressings for salad, or

(2) At least 1.7 g of plant stanol esters that comply with paragraph (c)(2)(ii)(B)(1) of this section per reference amount customarily

consumed of the food products eligible to bear the health claim, specifically spreads, dressings for salad, snack bars, and dietary supplements in softgel form.

(B) The food shall meet the nutrient content requirements in § 101.62 for a "low saturated fat" and "low cholesterol" food; and

(C) The food must meet the limit for total fat in § 101.14(a)(4), except that spreads and dressings for salad are not required to meet the limit for total fat per 50 g if the label of the food bears a disclosure statement that complies with § 101.13(h); and

(D) The food must meet the minimum nutrient contribution requirement in § 101.14(e)(6) unless it is a dressing for salad.

(d) Optional information.

(1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease.

(2) The claim may state that the relationship between intake of diets that include plant sterol/stanol esters and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total and LDL cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that include plant sterol/stanol esters and the risk of CHD and the significance of the relationship.

21 C.F.R. § 101.83

(4) The claim may include information from the following paragraph on the relationship between saturated fat and cholesterol in the diet and the risk of CHD: The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total and LDL cholesterol and, thus, with increased risk of CHD. Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL cholesterol levels.

(5) The claim may state that diets that include plant sterol or stanol esters and are low in saturated fat and cholesterol are consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(6) The claim may state that individuals with elevated blood total and LDL cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total and LDL cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(e) Model health claim. The following model

health claims may be used in food labeling to describe the relationship between diets that include plant sterol or stanol esters and reduced risk of heart disease:

(1) For plant sterol esters:

(i) Foods containing at least 0.65 g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ____ grams of vegetable oil sterol esters.

(ii) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 1.3 g of vegetable oil sterol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies ____ grams of vegetable oil sterol esters.

(2) For plant stanol esters:

(i) Foods containing at least 1.7 g per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ____ grams of plant stanol esters.

(ii) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 g of vegetable oil stanol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies ____ grams of vegetable oil stanol esters.

[65 FR 54717, Sept. 8, 2000; 65 FR 70466, Nov. 24, 2000; 70 FR 41958, July 21, 2005]

21 C. F. R. § 101.83, 21 CFR § 101.83

Current through July 19, 2007; 72 FR 39581

21 C.F.R. § 101.83

Thomson/West Copr. © 2007

END OF DOCUMENT

33

Westlaw.

Page 1

21 C.F.R. § 101.100

C

Effective: November 08, 2005

Code of Federal Regulations Currentness

Title 21. Food and Drugs

Chapter I. Food and Drug Administration,
Department of Health and Human Services
(Refs & Annos)

Subchapter B. Food for Human Consumption

Part 101. Food Labeling (Refs & Annos)

Subpart G. Exemptions from Food
Labeling Requirements (Refs & Annos)**→ § 101.100 Food; exemptions from
labeling.**

(a) The following foods are exempt from compliance with the requirements of section 403(i)(2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).

(1) An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption, however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as practicable and that are not misleading) indicating by name other ingredients which may be present.

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either:

(i) The labeling of the bulk container plainly in view, provided ingredient information appears prominently and conspicuously in lettering of

not less than one-fourth of an inch in height; or

(ii) A counter card, sign, or other appropriate device bearing prominently and conspicuously, but in no case with lettering of less than one-fourth of an inch in height, the information required to be stated on the label pursuant to section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act).

(3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(b) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(c) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting

21 C.F.R. § 101.100

food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(4) For the purposes of paragraph (a)(3) of this section, any sulfiting agent (sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite) that has been added to any food or to any ingredient in any food and that has no technical effect in that food will be considered to be present in an insignificant amount only if no detectable amount of the agent is present in the finished food. A detectable amount of sulfiting agent is 10 parts per million or more of the sulfite in the finished food. Compliance with this paragraph will be determined using sections 20.123-20.125, "Total Sulfurous Acid," in "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th Ed. (1984), which is incorporated by reference and the refinements of the "Total Sulfurous Acid" procedure in the "Monier-Williams Procedure (with Modifications) for Sulfites in Foods," which is Appendix A to Part 101. A copy of sections 20.123-20.125 of the Official Methods of Analysis of the Association of Official Analytical Chemists" is available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) A food repackaged in a retail establishment is exempt from the following provisions of the act if the conditions specified are met.

(1) Section 403(e)(1) of the act (requiring a statement on the label of the name and place of business of the manufacturer, packer, or distributor).

(2) Section 403(g)(2) of the act (requiring the label of a food which purports to be or is represented as one for which a definition and standard of identity has been prescribed to bear the name of the food specified in the definition and standard and, insofar as may be required by the regulation establishing the standard the common names of the optional ingredients present in the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required by these provisions.

(3) Section 403(i)(1) of the act (requiring the label to bear the common or usual name of the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

(c) An open container (a container of rigid or semirigid construction, which is not closed by lid, wrapper, or otherwise other than by an uncolored transparent wrapper which does not obscure the contents) of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than 1 dry quart, shall be exempt from the labeling requirements of sections 403(e), (g)(2)(with respect to the name of the food specified in the definition and standard), and (i)(1) of the act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance

21 C.F.R. § 101.100

with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will ensure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such food from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(3) The article is an egg product subject to a standard of identity promulgated in Part 160 of this chapter, is to be shipped under the conditions specified in paragraph (d)(1) or (2) of this section and for the purpose of pasteurization or other treatment as required in such standard, and each container of such egg product bears a conspicuous tag or label reading "Caution--This egg product has not been pasteurized or otherwise treated to destroy viable *Salmonella* microorganisms". In addition to safe and suitable bactericidal processes designed specifically for *Salmonella* destruction in egg products, the term "other treatment" in the first sentence of this paragraph shall include use in acidic dressings in the processing of which the pH is not above 4.1 and the acidity of the aqueous phase, expressed as acetic acid, is not less than 1.4 percent, subject also to the conditions that:

(i) The agreement required in paragraph (d)(2) of this section shall also state that the operator

agrees to utilize such unpasteurized egg products in the processing of acidic dressings according to the specifications for pH and acidity set forth in this paragraph, agrees not to deliver the acidic dressing to a user until at least 72 hours after such egg product is incorporated in such acidic dressing, and agrees to maintain for inspection adequate records covering such processing for 2 years after such processing.

(ii) In addition to the caution statement referred to above, the container of such egg product shall also bear the statement "Unpasteurized _____ for use in acidic dressings only", the blank being filled in with the applicable name of the eggs or egg product.

(e) Conditions affecting expiration of exemptions:

(1) An exemption of a shipment or other delivery of a food under paragraph (d)(1) or (3) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(2) An exemption of a shipment or other delivery of a food under paragraph (d)(2) or (3) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by paragraph (d)(2) or (3) of this section.

(3) An exemption of a shipment or other delivery of a food under paragraph (d)(2) or (3) of this section shall expire:

(i) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food constituting such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

21 C.F.R. § 101.100

(ii) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

(f) The word "processed" as used in this paragraph shall include the holding of cheese in a suitable warehouse at a temperature of not less than 35° F for the purpose of aging or curing to bring the cheese into compliance with requirements of an applicable definition and standard of identity. The exemptions provided for in paragraph (d) of this section shall apply to cheese which is, in accordance with the practice of the trade, shipped to a warehouse for aging or curing, on condition that the cheese is identified in the manner set forth in one of the applicable following paragraphs, and in such case the provisions of paragraph (e) of this section shall also apply:

(1) In the case of varieties of cheese for which definitions and standards of identity require a period of aging whether or not they are made from pasteurized milk, each such cheese shall bear on the cheese a legible mark showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each cheese, on its wrapper or immediate container, shall be affixed a removable tag bearing the statement "Uncured _____ cheese for completion of curing and proper labeling", the blank being filled in with the applicable name of the variety of cheese. In the case of swiss cheese, the date at which the preliminary manufacturing process had been completed and at which date curing commences is the date on which the shaped curd is removed from immersion in saturated salt solution as provided in the definition and standard of identity for swiss cheese, and such cheese shall bear a removable tag reading, "To be cured and labeled as 'swiss cheese,' but if eyes do not form, to be labeled as 'swiss cheese for manufacturing'".

(2) In the case of varieties of cheeses which when made from unpasteurized milk are required to be aged for not less than 60 days, each such cheese shall bear a legible mark on the cheese showing the date at which the

preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading, "_____ cheese made from unpasteurized milk. For completion of curing and proper labeling", the blank being filled in with the applicable name of the variety of cheese.

(3) In the case of cheddar cheese, washed curd cheese, colby cheese, granular cheese, and brick cheese made from unpasteurized milk, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading "_____ cheese made from unpasteurized milk. For completion of curing and proper labeling, or for labeling as _____ cheese for manufacturing", the blank being filled in with the applicable name of the variety of cheese.

(g) The label declaration of a harmless marker used to identify a particular manufacturer's product may result in unfair competition through revealing a trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(1) The person desiring to use the marker without label declaration of its presence has submitted to the Commissioner of Food and Drugs full information concerning the proposed usage and the reasons why he believes label declaration of the marker should be subject to this exemption; and

(2) The person requesting the exemption has received from the Commissioner of Food and Drugs a finding that the marker is harmless and that the exemption has been granted.

(h) Wrapped fish fillets of nonuniform weight intended to be unpacked and marked with the correct weight at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirement of

21 C.F.R. § 101.100

section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing and marking:

(1) *Provided*, That

(i) The outside container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at or before time of sale" and a correct statement setting forth the weight of the wrapper;

(2) *Provided further*, That it is the practice of the retail establishment to weigh and mark the individual packages with a correct net-weight statement prior to or at the point of retail sale. A statement of the weight of the wrapper shall be set forth so as to be readily read and understood, using such term as "wrapper tare--ounce", the blank being filled in with the correct average weight of the wrapper used.

(3) The act of delivering the wrapped fish fillets during the retail sale without the correct net-weight statement shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for wrapped fish fillets delivered into institutional trade provided the outside container bears the required information.

(i) Wrapped clusters (consumer units) of bananas of nonuniform weight intended to be unpacked from a master carton or container and weighed at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirements of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing:

(1) *Provided*, That

(i) The master carton or container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at or before the time of sale" and a correct statement setting forth the

weight of the wrapper; using such term as "wrapper tare ____ ounce", the blank being filled in with the correct average weight of the wrapper used;

(2) *Provided further*, That it is the practice of the retail establishment to weigh the individual packages either prior to or at the time of retail sale.

(3) The act of delivering the wrapped clusters (consumer units) during the retail sale without an accurate net weight statement or alternatively without weighing at the time of sale shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for clusters (consumer units) delivered into institutional trade, provided that the master container or carton bears the required information.

[51 FR 25017, July 9, 1986; 58 FR 2188, 2876, Jan. 6, 1993; 58 FR 17328, April 2, 1993; 66 FR 17358, March 30, 2001]

SOURCE: 42 FR 14308, March 15, 1977; 51 FR 25017, July 9, 1986; 52 FR 6971, March 9, 1987; 54 FR 39632, Sept. 27, 1989; 58 FR 2426, Jan. 6, 1993; 58 FR 17341, April 2, 1993; 59 FR 350, Jan. 4, 1994; 60 FR 67174, Dec. 28, 1995; 61 FR 43446, Aug. 23, 1996; 62 FR 3600, Jan. 23, 1997; 62 FR 15342, March 31, 1997; 62 FR 51513, Oct. 1, 1997; 65 FR 76110, Dec. 5, 2000, unless otherwise noted.

AUTHORITY: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

21 C. F. R. § 101.100, 21 CFR § 101.100

Current through July 19, 2007; 72 FR 39581

21 C.F.R. § 101.100

Thomson/West Copr. © 2007

END OF DOCUMENT

34

Westlaw.

Page 1

21 C.F.R. § 102.5

C

Effective: [See Text Amendments]

Code of Federal Regulations Currentness

Title 21. Food and Drugs

Chapter 1. Food and Drug Administration,
Department of Health and Human Services
(Refs & Annos)

Subchapter B. Food for Human Consumption

Part 102. Common or Usual Name for
Nonstandardized Foods (Refs & Annos)

Subpart A. General Provisions

→ § 102.5 General principles.

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in Subpart B of this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) ____ percent (or %) ____" or "____ percent (or %) ____" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "____ percent or %) ____" shall appear following or directly below the word "containing" (or contains), or directly below the part of the common or usual name of the food required by paragraph (a) of this section when the word "containing" (or contains) is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(c) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling

21 C.F.R. § 102.5

or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in Subpart B of this part.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) _____" or "containing (or contains) no _____" or "no _____" or "does not contain _____", with the blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (c)(1) and/or (2) of this section shall appear following or directly below the part of the common or usual name of the food required by paragraphs (a) and (b) of this section, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraphs (b)(2)(i) and (ii) of this section.

(d) A common or usual name of a food may be established by common usage or by establishment of a regulation in Subpart B of this part, in Part 104 of this chapter, in a standard of identity, or in other regulations in this chapter.

SOURCE: 42 FR 14322, March 15, 1977; 54 FR 39632, Sept. 27, 1989; 62 FR 51513, Oct. 1, 1997, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 343, 371.

21 C. F. R. § 102.5, **21 CFR § 102.5**

Current through July 19, 2007; 72 FR 39581

Copr. © 2007

Thomson/West

END OF DOCUMENT

35

Westlaw.

Page 1

21 C.F.R. § 102.33

C

Effective: [See Text Amendments]

Code of Federal Regulations Currentness

Title 21. Food and Drugs

Chapter I. Food and Drug Administration,
Department of Health and Human Services
(Refs & Annos)

Subchapter B. Food for Human Consumption

Part 102. Common or Usual Name for
Nonstandardized Foods (Refs & Annos)Subpart B. Requirements for Specific
Nonstandardized Foods**→§ 102.33 Beverages that contain
fruit or vegetable juice.**

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of § 102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with § 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

(c) If a diluted multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the

ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit juices.")

(d) In a diluted multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall:

(1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or

(2) Include the amount of the named juice, declared in a 5-percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice). The 5-percent range, when used, shall be declared in the manner set forth in § 102.5(b)(2).

(e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "decaffeinated, decolorized grape juice").

(f) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then the source fruits or vegetables from which the modified juice was derived may not be depicted on the label by vignette or other pictorial representation.

(g)(1) If one or more juices in a juice beverage is

21 C.F.R. § 102.33

made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a type size no less than one-half the height of the letters in the name of the juice.

Thomson/West

END OF DOCUMENT

(2) If the juice is 100 percent single species juice consisting of juice directly expressed from a fruit or vegetable whose Brix level has been raised by the addition of juice concentrate from the same fruit or vegetable, the name of the juice need not include a statement that the juice is from concentrate. However, if water is added to this 100 percent juice mixture to adjust the Brix level, the product shall be labeled with the term "from concentrate" or "reconstituted."

[45 FR 39250, June 10, 1980, as amended at 45 FR 80497, Dec. 5, 1980; 47 FR 11821, March 19, 1982; 58 FR 2926, Jan. 6, 1993; 58 FR 17103, April 1, 1993; 58 FR 44063, Aug. 18, 1993; 62 FR 15343, March 31, 1997]

SOURCE: 42 FR 14322, March 15, 1977; 54 FR 39632, Sept. 27, 1989; 62 FR 51513, Oct. 1, 1997, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 343, 371.

21 C. F. R. § 102.33, **21 CFR § 102.33**

Current through July 19, 2007; 72 FR 39581

Copr. © 2007

© 2007 Thomson/West. No Claim to Orig. U.S. Govt. Works.